K083674
p.1/2

PK-141 Patient Cable
510(k) Premarket Notification

APR - 1 2009

1. PATIENT CABLE 510(K) SUMMARY

Name and Address of Applicant:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number:

1028232

Device Name:

Proprietary Name: PK-141
Common Name: Programmer, Pacemaker (Accessories)
Classification: Class II (21 CFR 870.3700)
Classification Name: Cabling
Product Code: KRG

510(k) Number:

K022360

Date Prepared:

December 10, 2008

General Description:

The PK-141 patient cable is compatible with the following BIOTRONIK external equipment: ICS 3000 Implant Control System, EDP 20/30 B External Pacemakers, and ERA 300/3000 Pacing System Analyzers. The PK-141 is intended to connect to the patient's sensing and pacing leads. The PK-141 is connected to the Redel connector provided by the external equipment and the alligator clips connect to the electrode.
The PK-141 is made up of a 2.8m cable with four touch-proof alligator clips. The alligator clips are clamped directly to the tip or the contact ring of the leads. During its use, the cable is in the sterile field; therefore it must be sterile itself. Skin contact with the patient is not anticipated.

Predicate Device:

BIOTRONIK proposes the following programmer accessory cleared through 510(k) notification as the predicate device for the PK-141 cable:

- BIOTRONIK's PK-67-L (K022360 ERA 3000 Dual Chamber Pacing Analyzer, cleared January 27, 2003)

Indications for Use:

The PK-141 patient cable is an accessory indicated for use with external equipment from BIOTRONIK and is used for the transmission of sensing signals and pacing pulses for diagnostics and therapy in the context of intracardiac examinations including the following activities:

- Temporary External Pacing
  Provides temporary stimulation during implantable pacemaker procedures or physician evaluations.
- Lead Threshold Determination
  Determines in situ lead characteristics of impedance, capture threshold, P/R wave amplitude and P/R wave slew rate. Determines the in vivo retrograde conduction time.
- Pacemaker Function Test

Tests and analyzes the in vitro operation of external or implantable pulse generators. Determines the following parameters: pulse amplitude and width, A/V delay, and rate/interval.

Name and Address of Manufacturing Site:

BIOTRONIK GmbH & Co. KG
Woermannkehre 1
D-12359 Berlin, Germany

Manufacturer's Establishment Registration Number

9610139

510(k) Contact Person and Phone Number:

Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
(888) 345-0374

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2009

BIOTRONIK, Inc
c/o Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035

Re: K083674
Trade/Device Name: PK-141 Patient Cable
Regulation Number: 21 CFR 870.3700
Regulation Name: Programmer, Pacemaker (Accessories)
Regulatory Class: Class II (two)
Product Code: KRG
Dated: March 25, 2009
Received: March 26, 2009

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083674

Device Name: PK-141 Patient Cable

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083674